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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,544	09/23/2007	Yukimitsu Suda	TOS-172-USA-PCT	4499
27955 TOWNSEND &	7590 08/03/200 & BANTA	9	EXAMINER	
c/o PORTFOLIO IP			REDDICK, MARIE L	
	PO BOX 52050 MINNEAPOLIS, MN 55402		ART UNIT	PAPER NUMBER
			1796	
			MAIL DATE	DELIVERY MODE
			08/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/593,544	SUDA ET AL.				
Office Action Summary	Examiner	Art Unit				
	MARIE REDDICK	1796				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>09/20</u>	/06:04/10/07:09/23/07					
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	/ <del></del>					
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
	☐ Claim(s) <u>1-8</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>1-8</u> is/are rejected.						
7) Claim(s) <u>1 &amp; 5-8</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>20 September 2006</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other: <u>See Continuation Sheet.</u>						

Continuation of Attachment(s) 6). Other: Machine Translation (JP09-327288).

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#### **DETAILED ACTION**

### Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### **Drawings**

3. The drawings filed on 09/20/06 are accepted by the Examiner.

## Specification

- 4. The abstract of the disclosure is objected to because it houses paragraphs in excess of one. Correction is required. See MPEP § 608.01(b).
- 5. The disclosure is objected to because of the following informalities: On page 19 @ line 14, page 20 @ line 2, page 21 @ line 21, page 23 @ line 19, page 24 @ lines 7, 16 & 20, page 25 @ line 19, page 26 @ line 9, page 28, Table 1 and page 29, line 7, the units in which the temperature is measured is absent, e.g., "degrees C", in each of the above instances and the concentration of HCL per Table 2, each instance, is absent; In the "Treatment method 1" and "Treatment method 2" at page 19, lines 1-25 to page 20, lines 1-4, as far as the Examiner can tell, there appears to be steps missing in each of the treatment methods.

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Appropriate correction is required.

### Claim Objections

6. Claims 1 and 5-8 are objected to because of the following informalities: The recited [Chemical formula 1]-[Chemical formula 9], as far as the Examiner can tell, is inconsistent with the recited [Chemical formula 10]-[Chemical formula 18] in the specification. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) The recited "A method of manufacturing an eye lens material having a process" per claims 1 & 5-7 constitutes indefinite subject matter as per said recitation engenders awkwardly expressed claim language. Furthermore the metes and bounds of "having a process" engenders indeterminacy in scope.
- B) The recited "having OH groups in water, an organic solvent, or a water/organic solvent mixture" per claims 1 & 6 constitutes indefinite subject matter as per it not being readily ascertainable as to whether or not it is the reaction taking place in the aforementioned solvent(s) or if the "OH" groups are in the solvent(s). Perhaps use of "in water, an organic solvent, or a water/organic solvent mixture" after "reacted" would conceivably avoid any confusion. See also claims 7 & 8 in this regard.

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C) The recited "(1)" and "(2)" per claims 1 & 5-8 constitute indefinite subject matter as per it not being readily ascertainable as to how said parenthetical expressions further limit the antecedently recited [Chemical formula 1] - [Chemical formula 9].

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- D) The recited "constituent monomers" per claims 2-4 engenders awkwardly expressed claim language.
- E) The recited "constituent monomers— include polyvinyl alcohol" per claim 4 constitutes indefinite subject matter as per it not being readily ascertainable as to how the recited "polyvinyl alcohol" further limits the antecedently recited "monomers".
- F) The recited "characteristically obtained" per claim 6 constitutes indefinite subject matter as per it not being readily ascertainable as to if or how said objectionable term "characteristically" further limits the claims.
- G) Claims 1 & 6 constitute indefinite subject matter as per the reaction mechanism engendering unclarity, i.e., it is not readily ascertainable as to the no. of reactions intended.
- H) The recited "A protein adsorption prevention method" per claim 8 engenders an awkwardly expressed process. Use of "A method for preventing protein adsorption on an eye lens material" is *suggested*.

#### Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6 & 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koinuma et al (US 5,466,853).

Koinuma et al teach the use of a surface modifier, viz., a phosphorylcholine group-containing compound in a processing solution for treating contact lens which are derived from vinyl monomers which include 2-hydroxyethyl (meth) acrylate and wherein the solvent used in the contact lens processing solution includes water and/or organic solvent (Abstract, col. 1, lines 6-10, col. 2, lines 61-67, cols. 3-9 and cols. 19-20 (Run 5-1) of Koinuma et al and claims 6 & 7). Koinuma et al therefore anticipate the instantly claimed invention with the understanding the claimed invention houses a product-by-process limitation. "[E] ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Even if it turns out that the Examiner has somehow missed the boat and the claimed invention is not anticipated, it would have been obvious to the skilled artisan, at the time the invention was made, to extrapolate, from Koinuma et al, the precisely defined eye lens material as per such having been within the purview of the general disclosure of Koinuma et al and with a reasonable expectation of success.

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12. JP 09-327288 to SAKAKI et al and US Patent 5,936,703 to Miyazaki et al are cited as of being illustrative of the general state of the art.

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# Allowable Subject Matter

- 12. Claims 1-5 & 8 are deemed allowable.
- 13. Claims 1-5 & 8 would be allowed if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the Objections to the specification and claims as set forth in this Office action.
- 14. The following is a statement of reasons for the indication of allowable subject matter:

  The instantly claimed invention is deemed allowable over the prior art of record as per said art neither anticipating nor rendering obvious the precisely defined method of manufacturing an eye lens material (claims 1-5) and a method of preventing protein adsorption (claim 8). One having ordinary skill in the art would not have been endowed with any reasonable motivation to extrapolate, from any of the prior art of record, the precisely defined method of manufacturing an eye lens material (claims 1-5) and a method of preventing protein adsorption (claim 8) with any reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIE REDDICK whose telephone number is 2-5816. The examiner can normally be reached on 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DAVID WU can be reached on 2-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published

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automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MR 07/27/09

/David Wu/

Supervisory Patent Examiner, Art Unit 1796